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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,838	06/13/2005	Paolo Lombardi	40359/GM/lp	5659

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,838	LOMBARDI, PAOLO	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13* is/are rejected.

7)☒ Claim(s) *13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/13/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's response filed on 4/9/09. Applicant's election **with** traverse of the restriction requirement in the reply is acknowledged. The traversal is on the ground(s) that the PCT Search Authority did not raise a lack of unity objection for the original claims. This is not found persuasive because US restriction practice is different from those of the PCT. The requirement is still deemed proper and is therefore made FINAL. Claims 1-8 are cancelled. Claim 13 is added. Claim(s) 9-13 are pending. Claim(s) 9-13 are examined herein insofar as they read on the elected invention and species.

Application Formalities

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required. Applicant is required to filed an abstract.

Claim Objections

Claim 13 is objected to because of the following informalities: Claim 13 depends on claim 1, which has been cancelled. Appropriate correction is required. For examination purposes, claim 13 will be interpreted as being dependent on claim 9.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabled for the treatment of Coccidiosis by administering a compound of formula I, does not reasonably provide enablement for *preventing*. The specification does not enable any person skilled in the art to which it pertains to practice the invention commensurate in scope with these claims. Examiner notes that in the absence of a definition in the specification that prophylaxis is not prevention, the term "prophylaxis" will be interpreted as reading on prevention. For prior art rejection purposes, claim 9 will be interpreted as a method of treating Coccidiosis in an animal by administering a compound of formula I, where n is an integer from 1 to 4, R is NR3R4, R3 and R4 is H, A is -CONH-Z, Z is ethylene, and R1 is -C(=NH)-NH2.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the breadth of the claims; (4) the amount of direction or guidance presented; (5) the predictability or unpredictability of the art; (6) the relative skill of those in the art; (7)

the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention: The rejected claims are drawn to an invention which pertains to a method of preventing and treating Coccidiosis by administering a compound of formula I.

(2) State of the Prior Art: The state of the art regarding treating Coccidiosis by administering a compound of formula I is relatively high, however the state of the art for the prevention of Coccidiosis by administering a compound of formula I is non-existent.

(3) Breadth of Claims: The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass the prevention, inhibition, and treatment of Coccidiosis by administering a compound of formula I.

(4) Guidance of the Specification: The guidance of the specification as to the prevention of Coccidiosis by administering a compound of formula I is completely lacking. The specification discloses preventing the onset of Coccidiosis. However, the specification fails to mention how one is able to determine whether the onset of Coccidiosis in a subject would have occurred in the absence of treatment, thus being unable to confirm that prevention has indeed taken place. Moreover, the specification fails to mention the complete prevention or cessation of Coccidiosis once the onset of preclinically evident stage is determined.

(5) The Predictability or Unpredictability of the Art: The invention is directed to a method of treating, inhibiting, and preventing Coccidiosis by administering a compound

of formula I. The specification does not disclose how one of ordinary skill in the art at the time of the invention would be able to prevent Coccidiosis, nor does the prior art reveal any type of prevention associated with Coccidiosis.

(6) The Relative Skill of those in the Art: One of ordinary skill in the art does not know how to prevent Coccidiosis. Moreover, one is unable to determine whether a subject will ever develop a Coccidiosis should this subject be administered a compound of formula I.

(7) Working Examples: The specification does not give any data for the prevention of Coccidiosis by administering a compound of formula I.

(8) The Quantity of Experimentation Necessary: The specification fails to provide support for the prevention of Coccidiosis by administering a compound of formula I. Nor does it provide information to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.”

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,670,534. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite the treatment of endoparasitosis in an animal by administering a compound of formula I.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim(s) 9-10, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Animati et al. (US Patent 5,670,534, of record).

Animati et al. teach a method of treating diseases caused by parasites, for example, plasmodia, in humans by administering the antiparasitic agent of formula I, where n is an integer from 1 to 4, R is NR3R4, R3 and R4 is H, A is -CONH-Z, Z is ethylene, and R1 is -C(=NH)-NH2 (claims 1-7). The preferred embodiment is taught in Example 1 as 3-[1-Methyl-4-[1-methyl-4-[1-methyl-4-[1-methyl-4-(carboxyamido)pyrrol-

2-carboxyamido]pyrrol-2-carboxyamido]pyrrol-2-carboxyamido]pyrrol-2-carboxyamido] propionamidine hydrochloride. Animati et al. also teaches oral administration (col. 10, lines 49-50) in an amount 0.1 to 100 mg, 1 to 4 times per day (claim 7).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 11 and 13 are rejected under 35 U.S.C. 103(a) as being obvious over Animati et al. (US Patent 5,670,534, of record) as applied to claims 9-10, 12 in view of Applicant's admission of the prior art.

The instant claims are directed to a method of treating Coccidiosis in an animal by administering a compound of formula I, where n is an integer from 1 to 4, R is NR3R4, R3 and R4 is H, A is -CONH-Z, Z is ethylene, and R1 is -C(=NH)-NH2.

Animati et al. teach as discussed above, however, fail to disclose Coccidiosis.

Applicant's admission of the prior art teaches that Coccidiosis is caused by families of numerous intestinal parasites, and that it can develop world-wide in almost all domestic and wild animals, including humans (pg. 5, lines 14-16).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have treated an animal with Coccidiosis by administering a compound of formula I, where n is an integer from 1 to 4, R is NR3R4, R3 and R4 is H, A is -CONH-Z, Z is ethylene, and R1 is -C(=NH)-NH2.

A person of ordinary skill in the art would have been motivated to treat an animal with Coccidiosis by administering a compound of formula I, where n is an integer from 1 to 4, R is NR3R4, R3 and R4 is H, A is -CONH-Z, Z is ethylene, and R1 is -C(=NH)-NH2 because: (1) Animati et al. teach that the compound of formula I, where n is an integer from 1 to 4, R is NR3R4, R3 and R4 is H, A is -CONH-Z, Z is ethylene, and R1 is -C(=NH)-NH2 is an well-known and potent antiparasitic agent that can treat the diseases that the parasites causes; and (2) Applicant's admission of the prior art teaches that Coccidiosis is a well-known disease in animals caused by families of numerous intestinal parasites. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating Coccidiosis in an animal by administering a compound of formula I, where n is an integer from 1 to 4, R is NR3R4, R3 and R4 is H, A is -CONH-Z, Z is ethylene, and R1 is -C(=NH)-NH2.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S. Chong/
Primary Examiner, Art Unit 1617

YSC